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February 14, 2007

The Honorable Henry A. Waxman
Chairman
House Oversight and Government Reform Committee
2157 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Waxman:

On behalf of Teva Pharmaceuticals, we are pleased to endorse The Life Saving Medicine Act of 2007. We deeply appreciate your leadership in developing legislation to regulate the entry of safe and effective generic biologics into the U.S. marketplace.

This bill will create a regulatory pathway for the Food and Drug Administration to scientifically evaluate and approve generic biologics. As the leading generic pharmaceutical company, the goal of your legislation is consistent with our mission to develop and manufacture generic biologics to reduce the burden of the high cost of these products on the health care system and improve consumer access to these important medicines.

Specifically, we support:

- 1) Establishment of an approval process for generic biologics under the Public Health Services Act that ensures safety and efficacy without duplicative testing requirements.
- 2) Requiring approval of generic biologic applications on a case-by-case basis supported by rigorous scientific principles of comparability.
- 3) Promoting substitutability of generic biologics and their brand counterparts.
- 4) Establishing a mechanism for early resolution of legal disputes regarding relevant patents.

As health care costs in the United States continue to rise at a record pace, we look forward to working with you in securing passage of the The Life Saving Medicine Act of 2007 and to provide timely access to these affordable life-saving treatments.

Sincerely,

William S. Marth
President and CEO
Teva Pharmaceuticals USA